What is claimed:

1. An automated peritoneal dialysis system for performing continuous peritoneal dialysis of the type which includes repeated cycles of delivering sterile dialysate to a patient's peritoneal cavity and removing spent dialysate from the patient's cavity wherein said system comprises:

a dialysate preparation component providing a generally continuous supply of proportioned osmotic dialysate ready on demand which is effective for dialysis;

a fluid circuit connected to said dialysate supply for delivering a flow of the dialysate to the patient and a flow of spent dialysate from the patient to a drain;

an inflow line segment in said fluid circuit for delivering said dialysate from said supply to the patient;

a dialysate sterilization component having an in-line sterilization filter assembly disposed in said inflow line segment for real-time sterilization of said dialysate in said flow line segment during dialysis and prior to delivery of the dialysate to the patient's peritoneal cavity;

an outflow line segment included in said fluid circuit for connection to the patient to drain spent dialysate from the peritoneal cavity;

a filter integrity test component operatively associated with said sterilization filter assembly for conducting a realtime, in-line integrity test on said filter

assembly during dialysis to test for a filter failure which would allow contaminants into said dialysate prior to patient delivery;

a system sterilization component associated with said fluid circuit for sterilizing said fluid circuit including said dialysate sterilization component after a filter failure;

a control system controlling the filling and draining of the patient's peritoneal cavity to exchange a volume of dialysate until a desired fluid weight has been removed from the patient; and

said control system controlling said filter test component and said system sterilization component to test said sterilization filter assembly and sterilize the fluid circuit in the event of a filter failure.

2. The system of claim 1 including a proportioning component for adjusting the osmolality of said dialysate supply; and a proportioning sensor for determining the amount of fluid waste removed from the patient's peritoneal cavity during dialysis; and said control system controlling said proportioning component in response to said amount of removed fluid waste to adjust the osmoality of the dialysate as needed until a desired amount of waste is removed from the patient.

3. The system of claim 1 wherein said sterilization filter assembly includes an main inlet port for receiving unsterilized dialysate, a sterilization filter medium through which said dialysate passes for producing sterilized dialysate, a main outlet port through which sterilized dialysate flows; and said main inlet and outlet ports being connected in

said inflow line segment for delivery of said sterilized dialysate to the patient's peritoneal cavity.

4. The system of claim 3 wherein said filter testing component includes a source of pressurized test air to said sterilization filter assembly, a test air control valve having a normally closed position during dialysate flow, and said air control valve having an open position for delivering said test air to said filter assembly during said integrity test so that a real time integrity test of said sterilization filter assembly can be made prior to delivering of said dialysate into the peritoneal cavity.

5. The system of claim 4 wherein said main inlet port serves as an air admission port during said filter test, and said air control valve is arranged in said fluid circuit to selectively deliver dialysate and test air to said inlet port and filter medium.

6. The system of claim 4 including a pressure sensor in communication with said filter assembly for sensing said filter failure.

7. The system of claim 3 wherein said sterilization filter assembly includes a fluid outlet for delivery of unsterilized dialysate.

8. The system of claim 4 including a delivery vessel connected to said main outlet port of said sterilization filter assembly for accumulating said sterilized dialysate prior to delivery to said patient.

9. The system of claim 8 including a discard line segment included in said fluid circuit connected to said delivery vessel for discarding dialysate from said delivery vessel when said filter failure is sensed.

10. The system of claim 8 wherein said air control valve is set in said open position for delivering said pressurized air to said filter assembly after said sterilized dialysate has been delivered to said delivery vessel and prior to delivery of said dialysate to the patient.

11. The system of claim 8 wherein said sterilization filter assembly constitutes a primary sterilization filter assembly; and including a secondary sterilization filter assembly disposed in said fluid circuit, said secondary filter assembly having a main inlet port connected to said delivery vessel for receiving sterilized dialysate, a sterilization filter medium for sterilizing said dialysate, and a main outlet port for output delivery of said dialysate.

12. The system of claim 11 wherein said secondary filtration assembly is connected to said source of pressurized test air, and including a secondary test air control valve for admitting test air to the secondary filter assembly, and a secondary test sensor for detecting a failure condition of the secondary filter assembly upon the admission of test air to the secondary filter assembly for testing the integrity of the secondary filter assembly.

13. The system of claim 12 wherein said test control valve associated with said primary filter assembly is set in an open position to admit pressurized test air after said dialysate has passed through said primary filter assembly, and said secondary test control valve is set in an open position for admitting pressurized test air before passage of dialysate through said secondary filter assembly.

14. The system of claim 13 including a discard line segment in said fluid circuit for discarding dialysate passed through one or more of said filter assemblies when one or more of said filter fails said integrity test.

15. The system of claim 1 including a sterilization unit wherein said sterilization filter assembly is a primary filter assembly of said sterilization unit, and said sterilization unit includes a secondary sterilization filter assembly disposed in said fluid circuit, said secondary filter assembly having a main inlet port for receiving sterilized dialysate which has passed through said pimary filter assembly, a sterilization filter medium for sterilizing said dialysate, and a main outlet port for delivering dialysate to the patient's peritoneal cavity.

16. The system of claim 15 wherein said primary and secondary filtration assemblies are connected to a source of pressurized test air, and including primary and secondary test control valves for admitting pressurized air to the second filter assembly during said filter test while blocking off said air during flow of dialysate; and primary and secondary test sensors for detecting a filter failure of the primary and secondary filter assemblies upon the admission of pressurized air to said primary and secondary filter assemblies for testing the integrity of the filter assemblies prior to delivery of said dialysis fluid to the patient.

17. The system of claim 16 wherein said primary and secondary test control valves are set in an open position for admitting test air after said dialysate has passed through said primary filter assembly but before said dialysate is passed through said secondary filter assembly.

18. The system of claim 17 including a delivery vessel connected to said main outlet port of said primary filter assembly for holding said dialysate passed through said primary filter assembly during said integrity tests; and said delivery vessel being connected to said main inlet port of said secondary filter assembly for delivering said dialysate through said secondary filter assembly and to the patient after said integrity tests are passed.

19. The system of claim 18 including at least one discard line segment for discarding dialysate passed through said filter assemblies when either filter medium fails said integrity test.

20. The system of claim 15 including a first sterilization unit and a second sterilization unit connected in parallel in said inflow line, and valve control means for selectively delivering unsterilized dialysate through said second sterilization unit while sterilized dialysate from said first sterilization unit is delivered to said patient.

21. The system of claim 1 wherein said system sterilization component includes a automated sterilant control valve for admitting a sterilant solution to said main fluid circuit including said sterilization filter assembly to flush and resterilize the fluid circuit after a filter failure and replacement.

22. The system of claim 21 including a manual sterilant control valve preventing flow of said sterilant during dialysis, said manual control valve having an open position sterilant to flow to proportioning component to proportion said sterilant with sterile water for sterilizing said main circuit after completion of dialysis.

23. An automated peritoneal dialysis system for performing continuous peritoneal dialysis of the type which includes a fluid circuit for delivering sterile dialysate to the peritoneal cavity of a patient and removing spent dialysate from the patient; and a system controller for controlling the flow of dialysate during said fill and drain of dialysate wherein said system comprises:

a generally continuous supply of unsterilized dialysate for supplying large volumes of dialysate on demand;

an inflow line segment included in said fluid circuit for delivering dialysate from said supply to the patient;

an outflow line segment included in said fluid circuit for connection to the patient's peritoneal cavity to drain spent dialysate from the peritoneal cavity;

an in-line sterilization filter assembly disposed in said inflow line segment for realtime sterilization of said unsterilized dialysate during flow of said dialysate in said inflow line segment prior to patient delivery;

said sterilization filter assembly including an inlet port connected in said inflow line segment for receiving unsterilized dialysate, a sterilization filter medium through which said dialysate passes for producing sterilized dialysate, and an outlet port connected in said inflow line segment through which sterilized dialysate flows for delivery to the patient;

a filter test component operatively associated with said sterilization filter assembly for conducting a realtime integrity test on said filter assembly to test for a filter

failure condition which would allow contaminants into said dialysate prior to patient delivery; and

a test sensor in communication with said testing component for detecting said failure condition;

whereby large volumes of sterilized dialysate are available on demand in realtime during the peritoneal dialysis process to provide a high rate of dialysate exchange during repeated dialysate fill and drain cycles until a desired weight of fluid waste is removed from the patient.

24. The system of claim 23 wherein said test component includes a source of pressurized test air connected to said sterilization filter assembly, a test air control valve preventing admission of test air during dialysis, and said air control valve having an open position for delivering said test air to said filter assembly during said integrity test so that a filter integrity test of said sterilization filter assembly can be made in realtime prior to the injection of said dialysate into the peritoneal cavity.

25. The system of claim 24 wherein said air control valve is set in said open position for delivering said pressurized air to said filter assembly during said integrity test after said sterilized dialysate has been delivered to said delivery vessel and prior to delivery of said dialysate to the patient.

26. The system of claim 24 wherein said test sensor includes a pressure sensor in communication with said filter assembly for sensing a filter failure condition.

27. The system of claim 23 wherein sterilization filter assembly includes a fluid outlet for delivery of unsterilized dialysate.

28. The system of claim 23 wherein said fluid circuit includes a discard line segment for discarding dialysate passed through said filter assembly in the event said filter medium fails said integrity test.

29. The system of claim 28 including a delivery vessel connected to said outlet port of said sterilization filter assembly for accumulating said sterilized dialysate prior to delivery to said patient, and said discard line segment being connected to said delivery vessel.

30. The system of claim 23 wherein said dialysate is supplied for repeated drain and fill cycles, said sterilization filter assembly constitutes a first sterilization filter assembly; and including a second sterilization filter assembly connected in parallel to said first sterilization filter assembly, and a flow control arrangement for passing unsterilized dialysate thru said first and second sterilization filter assemblies in a cyclic manner so that sterilized dialysate from said first sterilization filter assembly is used during a present fill cycle and sterilized dialysate from said second sterilization filter assembly is used during a next fill cycle.

31. The system of claim 30 wherein said flow control arrangement selectively isolates one of said first and second sterilization filter assemblies from the other so that only one of said first and second filter assemblies is used during repeated fill cycles.

32. An automated peritoneal dialysis system for performing continuous peritoneal dialysis of the type which includes a fluid circuit for delivering sterile dialysate to a patient's peritoneal cavity and removing used dialysate from the patient; and a

system controller for controlling said filling and draining to achieve an effective dialysis, wherein said system comprises:

a steady supply of a large volume dialysate effective for dialysis available on demand;

an inflow line segment included in said fluid circuit for connection to the patient to deliver dialysate from said supply;

an outflow line segment included in said fluid circuit for connection to the patient to drain spent dialysate from the peritoneal cavity;

a sterilization unit included in said inflow line segment which includes:

a primary in-line sterilization filter assembly disposed in said inflow line segment for real-time sterilization of said dialysate during flow of said dialysate in said inflow line segment prior to patient delivery;

a secondary in-line sterilization filter assembly disposed in said inflow line segment for real-time sterilization of said dialysate during flow of said dialysate in said inflow line segment prior to patient delivery;

said primary sterilization filter assembly unit including an inlet port connected in said inflow line segment for receiving said dialysate from said supply, a sterilization filter medium through which said dialysate passes for producing sterilized dialysate, and an outlet port connected in said inflow line segment through which sterilized dialysate flows;

a delivery vessel included in said connected to said outlet port of said primary sterilization filter assembly for accumulating said dialysate;

said secondary filter assembly having an inlet port connected to said delivery vessel for receiving said accumulated ialysate, a sterilization filter medium for sterilizing said dialysate, and an outlet port for delivering dialysate to the patient; and

a filter test component operatively associated with said primary and secondary sterilization filter assemblies for conducting a real-time integrity test on said filter assemblies to test for a filter failure condition which would allow contaminants into said dialysate prior to patient delivery;

whereby filling and draining of the peritoneal cavity with dialysate may be repeated by the system controller as needed using a realtime supply of sterilized dialysate ready on demand providing a high rate of dialysate exchange.

33. The system of claim 32 wherein said fluid circuit includes at least one discard line segment for discarding dialysate passed through said primary and secondary filter assemblies in the event one of said first and second filter mediums fails said filter failure condition.

34. The system of claim 33 wherein said discard line segment is connected to said delivery vessel.

35. The system of claim 32 wherein said primary and secondary filter assemblies are connected to a source of pressurized air, and including primary and secondary test control valves for selectively admitting pressurized air to the primary and secondary filter assemblies, and including primary and secondary test sensors for detecting said failure condition of the primary and secondary filter assemblies upon the

admission of pressurized air to said primary and secondary filter assemblies for testing the integrity of the filter assemblies prior to delivery of said dialysis fluid to the patent.

36. The system of claim 35 wherein said primary and secondary test control valves are set in said open position for delivering said pressurized air to said filter assemblies during said integrity test after said sterilized dialysate has been delivered to said delivery vessel and prior to delivery of said dialysate to the patient.

37. The system of claim 35 wherein said test control valves are set in said open position before said dialysate is passed through said secondary filter assembly.

38. The system of claim 32 including a pair of said sterilization units connected in parallel in said inflow line segment wherein each one of sterilization units includes said primary and secondary sterilization filter assemblies, and said delivery vessel; and including flow control means for passing said dialysate thru a selected one of said sterilization units while isolating said other of said sterilization units from said inflow line segment.

39. An automated peritoneal dialysis process for performing continuous peritoneal dialysis of the type which includes providing a supply of sterile dialysate to fill the patient's peritoneal cavity and removing spent dialysate from the patient's cavity, said process comprising the steps of:

(a) providing a generally continuous supply of large volumes of unsterilized dialysate;

(b) passing said unsterilized dialysate from said supply through an in-line sterilization filter assembly to produce sterilized dialysate in realtime during the process prior to delivery to the patient's peritoneal cavity;

(c) accumulating said sterilized dialysate in a delivery vessel prior to delivery to the patient;

(d) subjecting said in-line filter assembly to a realtime filter integrity test during the process to test for a filter failure that would allow contaminants into said dialysate prior to patient delivery;

(e) delivering said sterile dialysate from said delivery vessel to the patient's peritoneal cavity after said filter integrity test is passed; and

(f) repeating steps (a) through (e) until a desired volume of dialysate is exchanged.

40. The process of claim 39 including discarding said dialysate from said delivery vessel in the event said filter integrity test is not passed.

41. The process of claim 39 wherein said filter assembly is subjected to said filter integrity test after said dialysate is passed through said filter assembly and before delivery of said dialysate to the patient.

42. The process of claim 39 wherein said sterilization filter assembly constitutes a first filter assembly, and including providing a second sterilization filter assembly through which dialysate may be passed for sterilization.

43. The process of claim 42 including providing said first and second sterilization filter assemblies connected in parallel so that said dialysate may be

selectively passed through either filter assembly while isolating said other filter assembly.

44. The process of claim 42 wherein said process includes accumulating said dialysate which has been passed through said primary sterilization filter assembly in said delivery vessel, and delivering said dialysate from the delivery vessel through said secondary sterilization filter assembly to sterilize said dialysate in real-time prior to entering the patient's peritoneal cavity.

45. The process of claim 44 including testing said primary and secondary filter assemblies for filter failure which would allow contaminants into said dialysate after said dialysate is passed through said primary filter assembly and before said dialysate is passed through said secondary filter assembly prior to patient delivery.

46. The process of claim 45 including delivering said sterile dialysate from the delivery vessel through said secondary sterilization filter assembly to the peritoneal cavity of a patient after the filter failure test is passed, and discarding said dialysate from the delivery vessel in the event the filter failure test is not passed.

47. The process of claim 39 including:

determining the amount of said sterile dialysate delivered into the peritoneal cavity of a patient;

generating a first signal determined from the amount of said sterile dialysate delivered to the peritoneal cavity of a patient;

draining spent dialysate from the patient's peritoneal cavity;

determining the amount of spent dialysate drained from the peritoneal cavity of a patient;

generating a second signal determined from the amount of spent dialysate drained from the peritoneal cavity of a patient;

controlling the delivery of said sterile dialysate to the peritoneal cavity of a patient in response to said first and second signals until a desired volume of body fluid is removed from the peritoneal cavity of a patient.

48. The process of claim 47, wherein said process further comprises the step of calculating the amount of the body fluid waste removed from the patient after totally draining said dialysate for proportioning an amount of osmotic substance in said dialysate for subsequent fill and drain cycles.

49. In a continuous, cyclic peritoneal dialysis process, an in-line, realtime dialysis fluid sterilization process to produce a sterilized dialysate comprising:

preparing an unsterilized osmotic dialysate effective for dialysis;

passing said dialysate through at least one in-line sterilization filter assembly connected in an inflow line to the patient in realtime during the process prior to delivery to the patient; and

testing said sterilization filter assembly in realtime during the process for a filter failure condition prior to delivering said dialysate to the peritoneal cavity of the patient.

50. The process of claim 49 including accumulating the dialysate after passing the dialysate through said sterilization filter assembly, testing the integrity of said

sterilization filter assembly while the dialysate is accumulated and discarding the accumulated dialysate if the integrity test is failed.

51. The process of claim 49 including providing a sterilization unit having a primary sterilization filter assembly and a second sterilization filter assembly, passing said dialysate through said primary sterilization filter assembly, accumulating said dialysate, testing the integrity of said primary sterilization filter assembly, before passing said dialysate through said secondary sterilization filter assembly.

52. The process of claim 51 including testing the integrity of said secondary filter assembly before passing said dialysate through said secondary filter assembly.

53. The process of claim 52 including discarding said dialysate after being accumulated if one or more of said filter assemblies fails said integrity test.

54. The process of claim 51 including providing a pair of said sterilization units connected in parallel in said inflow line segment wherein each one of the sterilization units includes a primary and a secondary sterilization filter assembly, and a delivery vessel.

55. The process of claim 54 including passing the dialysate through a selected one of the sterilization units while isolating the other sterilization unit from the inflow line segment.

56. The process of claim 54 including selecting one of said sterilization units for the passage of dialysate in a cyclic manner so that one of the sterilization units is used during a current fill cycle, while the other unit is used to prepare and sterilize another batch of dialysate for use in the next fill cycle.

57. The process of claim 49 wherein testing of said sterilization filter assembly includes the steps of:

providing a source of sterile pressurized air for connection to said in-line sterilization filter assembly;

purging an upstream side of said filter assembly upstream of said peritoneal cavity with sterile pressurized air;

isolating said filter assembly upstream of said peritoneal cavity allowing the pressure to stabilize; and

monitoring the pressure decay for a given period of time.

58.. The process of claim 49 including providing first and second filter assemblies in parallel flow arrangement in said fluid circuit; and passing dialysate thru said first filter assembly and accumulating said dialysate in a first delivery vessel, subjecting said first filter assembly to an integrity test, and delivering said dialysate to said patient if the test is passed in a current fill cycle; and passing dialysate thru said second filter assembly and accumulating said dialysate in a second delivery vessel, subjecting said first second assembly to an integrity test, and delivering said dialysate from said second delivery vessel to said patient if the test is passed during a next fill cycle.

59. The process of claim 49 comprising the steps of:

carrying out said automated peritoneal dialysis process using an automatic peritoneal dialysis machine having a fluid circuit;

providing a sterilant solution to sterilize said peritoneal dialysis machine;

providing sterile water to sterilize said peritoneal dialysis machine;

flushing said continuous peritoneal dialysis machine with said sterilant solution; and

flushing said peritoneal dialysis machine with said sterile water.

60. The process of claim 59 including pressurizing said sterilant solution to force opposing flow of said sterilant through said in-line sterilization filter assembly to dislodge accumulated residue on the filter medium.

61. The process of claim 59 including pressurizing said sterile water to force opposing flow of said water through said in-line sterilization filter assembly to dislodge accumulated residue on the filter surface membrane.